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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/747,521
Filing Date	12/21/2000
First Named Inventor	Galloway
Art Unit	1645
Examiner Name	Patricia Ann Duffy
Attorney Docket Number	22727/04079

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):
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<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Calfee, Halter & Griswold LLP	Customer No. 24024
Signature		
Printed name	Joan N. Drew	
Date	03/29/2006	Reg. No. 52,364

### CERTIFICATE OF TRANSMISSION/MAILING

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Signature		
Typed or printed name	Jody K. Prince	Date 03/29/2006

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Typed or Printed name of person signing this certificate:

Signed: Jody K. Prince

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Galloway et al.	)      Examiner: Patricia Ann Duffy
	)
	)
Serial No.: 09/747,521	)      Art Unit: 1645
	)
Filed: 12/21/2000	)
	)
For: <b>Methods for Protection Against Lethal Infection with Bacillus Anthracis</b>	)      Attorney Docket No.: 22727/04079
	)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This information disclosure statement is being filed after the mailing of a first Office Action on the merits. Applicants wish to disclose the following information:

REFERENCES

- The Applicants wish to make of record the references listed on the attached Form PTO-8. copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references. Copies of the following references are enclosed for the Examiner's convenience: International Search Report, Written Opinion, and International Preliminary Examination Report for PCT/US00/34912; European Search Report and Examination Report for EP 00099028.2; Examiner's first Report of 10/07/2004 and second Report of 10/14/2005 in Australian Application 27329/01; Office Actions of 10/01/2002, 05/07/2003, and 11/21/2005 for U.S. serial no. 10/106,014; and Office Actions of 10/01/2002, 05/12/2003, and 11/18/2005 for U.S. Serial No. 10/105,694; and Office Actions of 07/16/2002, 05/29/2003, and 11/21/2005 for U.S. serial no. 10/105,695.

- Listed on the attached PTO form 8 is information known to persons substantively involved in the preparation of the application identified above, and is not a representation that more pertinent information does not exist.
- The identification of any information herein is not intended to be, and should not be understood as being, an admission that such information, in fact, constitutes "prior art" within the meaning of applicable law. The "prior art" status of any information is a matter to be resolved during prosecution.

**CERTIFICATION**

- Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.
- This information disclosure statement is being filed subsequent to a first Office Action on the merits being received.

**PETITION**

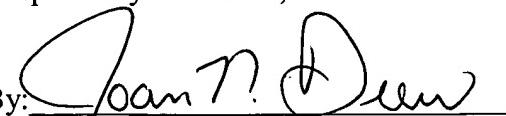
- Applicants hereby request consideration of the attached information.

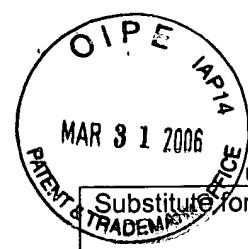
**DEPOSIT ACCOUNT**

- A check is attached in the amount of \$ 180.00 required under 37 § 1.17(p).
- The Patent Office is hereby authorized to charge deficiency or credit any overpayment to **Deposit Account No. 03-0172.**

Date: March 29, 2006

Respectfully submitted,

By:   
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(614) 621-0010 facsimile  
[jdrew@calfee.com](mailto:jdrew@calfee.com)



MAR 31 2006

PTO/SB/08B (08-03)

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Approved for use through January 1, 2003. GPO: 2001-0001  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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~~Substitute~~ for form 1449/PTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICATION**

(Use as many sheets as necessary)

Sheet 1 of 3

Substitute for form 1449/PTO <i>TRADEMAKES</i>				<b>Complete if known</b>
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICATION</b>				Application Number
				09/747,521
				Filing Date
				12/21/2000
				First Named Inventor
				Galloway
				Art Unit
				1645
				Examiner's Name
				Patricia Ann Duffy
(Use as many sheets as necessary)				Attorney Docket Number
Sheet	1	of	3	22727/04079

U.S. PATENT DOCUMENTS

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		WO 99/50439	10/07/99	Duesbery et al.		
		WO 92/19720	11/12/92	Mock et al.		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICATION**

(Use as many sheets as necessary)

Sheet	2	of	3	<b>Complete if known</b>
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Application Number	09/747,521
Filing Date	12/21/2000
First Named Inventor	Galloway
Art Unit	1645
Examiner's Name	Patricia Ann Duffy

Attorney Docket Number	22727/04079
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		BROSSIER, "Functional analysis of the carboxy-terminal domain of bacillus anthracis protective antigen," <u>Infection and Immunity</u> (Feb. 1999) vol. 67, no. 2, pp 964-967.	
		FENG, et al., "P55, an Immunogenic but nonprotective 55-Kilodalton Borrelia burgdorferi Protein in murine lyme disease," <u>Infect. Immun.</u> (1996) Volume 64, No. 1, pages 363-365.	
		HAMMOND, et al., "Lethal factor active-site mutations affect catalytic activity in vitro," <u>Infection and Immunity</u> , (May 1998), vol. 66, no. 5, pp 2374-2378.	
		HERBERT, et al. "The Dictionary of Immunology", Academic Press (1995).	
		HOUGHTEN, et al., "Relative importance of position and individual amino acid residues in peptide antigen-antibody interactions: implications in the mechanism of antigenic drift and antigenic shift," <u>Vaccines</u> (1986) Volume 86, pages 21-25.	
		MCGUINNESS, et al., "Class 1 outer membrane protein of Neisseria meningitidis: epitope analysis of the antigenic diversity between strains, implications for subtype definition and molecular epidemiology," <u>Mol. Microbiol.</u> (1993) Volume 7, pages 505-514.	
		MCGUINNESS, et al., "Point mutation in meningococcal por A gene associated with increased endemic disease," <u>The Lancet</u> (1991) Volume 337, pages 514-517.	
		PRICE, et al., "Genetic diversity in the protective antigen gene of bacillus anthracis," <u>Journal of Bacteriology</u> , (Apr. 1999), vol. 181, no. 8, pp. 2358-2362	
		ROTHEL, et al., "Sequential nucleic acid and recombinant adenovirus vaccination induces host-protective immune responses against <i>Taenia ovis</i> infection in sheep," <u>Parasite Immun.</u> (1997) Volume 19, pages 221-227.	

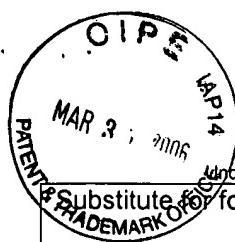
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# INFORMATION DISCLOSURE STATEMENT BY APPLICATION

(Use as many sheets as necessary)

Sheet	3	of	3	Attorney Docket Number	22727/04079
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		TONELLO, et al. "Tyrosine-728 and glutamic acid-735 are essential for the metalloproteolytic activity of the lethal factor of bacillus anthracis," <u>Biochemical and Biophysical Research Communications</u> , 313 (2004) pp 496-502.	
		VARUGHESE, et al. "Identification of a receptor-binding region within domain 4 of the protective antigen component of anthrax toxin," <u>Infection and Immunity</u> , (Apr. 1999) vol. 67, no. 4, pp 1860-1865.	

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